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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,459	01/31/2005	Noel Martin Young	025786-000100US	7643

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,459	Young, Noel Martin	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *6 and 10-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9 and 33-40* is/are rejected.

7)☒ Claim(s) *38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-40 are pending.

Claims 1-5, 7-9 and 33-40 are under consideration.

Claims 6, 10-32 stand withdrawn from consideration.

Withdrawn/ Sequence Letter/Sequence Requirements

1. Applicant submitted a sequence listing that was accepted the SEQ ID NOs and sequence identifiers were inserted into the instant Specification pages 15,16,18 and 20; and the Brief Description of the Drawing for the sequences shown in figure 3/12.

Response to Arguments

1. Applicant's arguments filed February 28, 2008 have been fully considered but they are not persuasive. ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Maintained, The rejection of claims 1,2,4-5 and new claims 33, 35-36 under 35 U.S.C. 102(a) as being anticipated by Linton et al (January 2002) in light of evidence provided by Szymanski et al (1999) is traversed on the grounds that the "fragment"

recited in the claims relative to the applied prior art "contain no information regarding activity against Campylobacter (Applicant's Remarks, page 7, last paragraph).

4. It is the position of the examiner that Linton et al disclose the instantly claimed invention directed to a compound that comprises N-acetylgalactoseamine (see title), the compound being from **Campylobacter jejuni** (see title), and is linked to an amino acid, either **serine or threonine** (see page 505, line 1) in a protein (PEB3 or CgpA, see page 505, col. 1, paragraph 3) of Campylobacter jejuni (see "glycoprotein", title).

5. The N-acetylgalactoseamine compound is immunologically active as it induced antibodies and was immunoreactive (see page 502, col. 2, last paragraph, figure 6(a) page 503; page 504 "they are highly immunogenic proteins with antibodies raised against glycan rather than amino acid epitopes (Szymanski et al, 1999"). Linton et al anticipates the instantly claimed invention as now claimed in light of evidence provided by Szymanski et al, 1999.

6. Maintained, The rejection of claims 1-5 and new claims 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Szymanski et al (1999) in light of evidence provided by Guerry et al (US PG-Pub 2007/0065461) is traversed by stating: "It is true, in the broadest sense, that these references disclose peptides having two or more bases, which conceivably could be considered fragments of many compounds, including the compound of claim 1."

7. It is the position of the examiner that the compound of claim 1 is not a peptide, nor a polypeptide, nor a protein, but a heptasaccharide. A saccharide is not a peptide

made up of amino acid bases. Applicant's traversal is not commensurate in scope with what is not claimed.

8. Applicant further characterizes the application of Szymanski et al as being directed fragments and states " [P]ractically all of the cited references disclose what might be termed "fragments" of the claimed compound but contain no information regarding activity against Campylobacter."

9. It is the position of the examiner that Szymanski et al was not applied against the claims because the claims recite the term "fragment", but because the reference isolated C.jejuni saccharide, specifically a highly immunogenic glycan molecule that is linked to numerous proteins that are immunodominant and therefore capable of generating antibodies active against Campylobacter.

10. Applicant further traverses the application of Szymanski et al by asserting the rejection was made in "combination with Guerry et al"... and concludes "Guerry et al is from the Young et al. publication... which the examiner recognizes as not being prior art".

11. It is the position of the examiner that the rejection of the claims over Szymanski et al (1999) was an inherency rejection, and Guerry et al was cited as extrinsic evidence of the inherent characteristics of the Campylobacter jejuni glycan heptasaccharide.

12. See MPEP section 2124 that states "the critical date of extrinsic evidence showing a universal fact need not antedate the filing date." Guerry et al was used as extrinsic evidence to show the universal fact that the saccharide glycan of Campylobacter

jejuni is in fact a heptasaccharide that is linked to numerous proteins through amino acids, the heptasaccharide being isolated from Campylobacter jejuni and was capable of generating antibodies active against Campylobacter jejuni. The prior art rejection is maintained for reasons of record and responses set forth herein. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, *the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new* to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

13. Maintained, The rejection of claims 1-2, 7, 9 and new claims 33-34, 37-38 and 40 under 35 U.S.C. 102(e) as being anticipated by Bay et al (filing date 1999) is traversed on the grounds that the reference contains no information regarding activity against Campylobacter.

14. It is the position of the examiner that a recited intended used of a composition does not structurally nor functionally change the basic chemical structure of the compound composition. The saccharide linked to an amino acid of Bay et al was able to generate an antibody to GalNAc. Absent evidence to the contrary, the antibody generated to alpha-GalNAc would be active against Campylobacter as the instantly claimed heptasaccharide comprises this terminal sugar which is known to be immunogenic. Bay et al inherently anticipates the instantly claimed invention as now claimed.

15. Bay et al disclose a compound that comprises a fragment of the compound of claim 1, specifically alpha-GalNAc linked to an amino acid, the amino acid being either threonine or Serine (see claims 1-3), the conjugate being formulated into an immunogenic compositions, with a suitable carrier and adjuvant (see claims 2-3).

16. Maintained, The rejection of claims 1-3 and new claims 33-34 under 35 U.S.C. 102(e) as being anticipated by Pugia et al (filed June 12, 2002) is traversed on the grounds that the reference contains no information regarding activity against Campylobacter.

17. It is the position of the examiner that a recited intended used of a composition does not structurally nor functionally change the basic chemical structure of the compound composition. The saccharide linked to an Asparagine in an oligopeptide of Pugia et al is capable of generating an antibody thereto. Absent evidence to the contrary, Pugia et al inherently anticipates the instantly claimed invention as now claimed. Pugia et al discloses the instantly claimed invention directed to a compound that comprises an immunologically active fragment, the fragment being GalNAc linked to asparagines (Asn) in an oligopeptide (see page 2, [0021] Y= GalNAc and X=Amino acid the compound being GalNAc-Asn-AminoAcid-Ser). Pugia et al anticipates the instantly claimed compound as now claimed.

18. Maintained, The rejection of claims 1-2, 7 and 9 and new claims 33, 37-38 under 35 U.S.C. 102(b) as being anticipated by Nilsson et al (Publication date 2000) is traversed on the grounds that the reference contains no information regarding activity against Campylobacter.

19. It is the position of the examiner that a recited intended used of a composition does not structurally nor functionally change the basic chemical structure of the compound composition. The saccharide linked to an amino acid of Nilsson et al et al is capable of generating an antibody thereto. Absent evidence to the contrary, Nilsson et al inherently anticipates the instantly claimed invention as now claimed.

20. Nilsson et al disclose a compound that comprises a fragment of the compound of claim 1, specifically alpha-GalNAc linked to an amino acid, the amino acid being either threonine or Serine (see page 3, bottom half of page, lines 42-55, [0010]), the conjugate being formulated into a composition [0026], with a suitable carrier (see 5, line 17 "water with buffer salts") and is disclosed to further comprise an additional peptide, protein or other spacer molecule [0019] . Nilsson et al anticipates the instantly claimed invention directed to compounds that comprise fragments of the compound of claim 1.

21. Maintained, The rejection of claims 1-2, and new claim 33 under 35 U.S.C. 102(b) as being anticipated by Messner et al (1990) is traversed on the grounds that the reference contains no information regarding activity against Campylobacter.

22. It is the position of the examiner that a recited intended used of a composition does not structurally nor functionally change the basic chemical structure of the compound composition. The saccharide linked to an amino acid of Messner et al is capable of generating an antibody thereto. Absent evidence to the contrary, Messner et al inherently anticipates the instantly claimed invention as now claimed.

23. Maintained, The rejection of claims 1-2 and new claims 33 and 35 under 35 U.S.C. 102(b) as being anticipated by US Pat. 5,840,547 in light of evidence provided by Gutnick et al (US Pat. 6,512,014) is traversed on the grounds that the reference contains no information regarding activity against Campylobacter.

24. It is the position of the examiner that US Pat. 5,840,547 disclose a Bac compound referred to a emulsan,(in light of evidence provided by Gutnick et al (Brief summary test, paragraph 6) emulsan is a compound that comprises Bac, also known as bacillosamine), wherein US Pat. 5,840,547 discloses Bac (emulsan) covalently linked to

an amino acid, specifically alanine (see Brief summary text, paragraphs 7 and 12 of US Pat. 5,840,547). US Pat. 5,840,547 anticipates the instantly claimed invention directed to compounds that comprise fragments of the compound (Bac) of claim 1 and new claim 33, linked to an amino acid (alanine).

25. The purification or production of a product by a particular process (i.e. the instant recombinant) does not impart novelty or unobviousness to a product when the product is taught by the prior art. This is particularly true, when the properties of the product are not changed by the process in an unexpected manner. *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); and *In re Brown*, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught by the prior art. *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 559, 601, 38 USPQ 143-45 (CCPA 1938); and *United States v. Ciba-Geigy Corp.*, 508 F.supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

26. Maintained, The rejection of claims 1, 7-9 and new claims 33, 37-40 under 35 U.S.C. 102(b) as being anticipated by Kaplan et al (WO 00/51635) in light of evidence provided by Gutnick et al (US Pat. 6,512,014), is traversed on the grounds that the reference contains no information regarding activity against Campylobacter.

27. It is the position of the examiner that a recited intended used of a composition does not structurally nor functionally change the basic chemical structure of the compound composition. The Bac linked to an amino acid of by Kaplan et al is capable

of generating an antibody thereto. Absent evidence to the contrary, by Kaplan et al inherently anticipates the instantly claimed invention as now claimed in light of extrinsic evidence provided by Gutnick et al.

(Instant claim 1)Kaplan et al disclose a compound that comprises Bac, specifically emulsan (see '635, page 2, line 11) (Gutnick et al provide evidence (Brief summary test, paragraph 6) that emulsan is a compound that comprises Bac, also known as bacillosamine, linked to an amino acid), formulated together with an antigen (see page 6, lines 10-11)

Instant claim 7, 37-38: into a pharmaceutical composition, the composition further comprising a physiologically acceptable carrier (see page 18, lines 28-30 " in combination with other physiologically acceptable medium (e.g., water, buffered saline, polyols such as glycerol, propylene glycol, liquid polyethylene glycol and dextrose solutions)",

Instant claim 8, 39: and immunoconjugate (see '635, page 8, lines 10-13 : antigen linked to an additional carrier such as bovine serum albumin (BSA) or keyhole limpet hemoxyanin (KLH); and claim 13, page 41)

Instant claim 9, 40: the antigen carrier being an immunostimulant (KLH).

Kaplan et al still anticipates the instantly claimed invention as now claimed for reasons of record and responses set forth herein

New Claims/New Grounds of Rejection/Objection

Specification

28. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Objections

29. Claim 38 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 38 recites the phrase "further comprising a physiologically acceptable carrier" and depends upon claim 37 which already comprises "a physiologically acceptable carrier"; the carriers have not been distinguished one from the other. Both carriers appear to be the same carrier. The carrier of claim 38 is not an additional carrier. Claim 38 is not further limiting of claim 37 from which it depends.

Claim Rejections - 35 USC § 101

30. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

31. New Claims 33 and 34 are rejected as previously applied to claims 1-5, as the claims are directed compounds that are not isolated and purified compounds and therefore do not show the hand of man; the claimed invention is directed to non-statutory subject matter. While claim 4 is directed to a product defined by product-by-process language, the product compound is not isolated and purified, and therefore still reads on a product of nature. This rejection could be obviated by amending the claims to recite the phrase -----An isolated and purified compound------ or --------A composition comprising an isolated and purified compound---------.

Claim Rejections - 35 USC § 112

32. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

33. Claims 4 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

34. Claim 4 and new claim 35 have been amended to recite product by process language for obtaining the claimed compound being derived from "a bacterium".

35. The examiner upon reconsideration of the instant Specification found narrative teaching the heptasaccharide being derived from Campylobacter species and numerous strains to include Cj nos 0114, 0200c, 0289c, 0367c (page 3, lines 15-19) and on page 4, lines 11-12, to be derived from "gram negative bacterium", as well as C.coli strain HS:30 (page 16, line 29), but the examiner could not find original descriptive support for obtaining the instantly claimed compound from any bacterium, to include gram positive bacteria, mycoplasma, acid fast bacteria to name a few. Therefore the instantly claimed genus of bacteria from which the claimed heptasaccharide can be derived has not been described in such a way as to convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Therefore, claims 4 and 35 recite New Matter. Amendment of these claims to recite Campylobacter

strains and species or a combination of claim limitations which evidence original descriptive support could obviate this rejection.

Conclusion

36. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
April 8, 2008

/Mark Navarro/
Primary Examiner, Art Unit 1645